IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

International Union of Bricklayers and Allied Craft Workers Local 1 Health Fund, individually and on behalf of all others similarly situated, **Plaintiff,** **v.** **Celgene Corporation,** **Defendant.**	**Civil Action No. 14-6997-KSH-CLW**

PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO CELGENE CORPORATION'S MOTION TO DISMISS CLASS ACTION COMPLAINT

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PRELIMINARY STATEMENT

Plaintiff International Union of Bricklayers and Allied Craft Workers Local 1 Health Fund ("IUB" or "Plaintiff") has sued to recover damages for years of Celgene's anticompetitive conduct and unfair business practices that prevented generic competition in the markets for two of its most expensive drugs – Thalomid and Revlimid. Over the last seven years, multiple generic competitors have been thwarted by Celgene's anticompetitive scheme, which involves, *inter alia*, abuse of the regulatory process in refusing to allow access to samples of the drugs for testing, fraud on the U.S. Patent Office (PTO), and the filing of sham patent infringement litigation.

In its Motion to Dismiss (a motion that it has lost four times against competitors), Celgene argues that its patents – not its anticompetitive conduct – have prevented competition. In essence, Celgene posits future, hypothetical patent litigation and argues that it would prevail in that theoretical litigation, thus blocking generic entry *lawfully*. Celgene's argument contradicts the well-pleaded facts of the complaint (including allegations of sham litigation and fraud on the patent office which eviscerate any purported *Noerr-Pennington* immunity) and ignores the well settled principle that, at the motion to dismiss phase, the plaintiff is not required to "adduce proofs discrediting all possible intervening causes of the delayed launch of generic products." *In re Neurontin Antitrust Litig.*, No. 02-1390,

2009 WL 2751029, at *12 (D.N.J. Aug. 28, 2009); *see also In re Lipitor Antitrust Litig.*, No. 3:12-CV-2389 PGS, 2013 WL 4780496, at *24 (D.N.J. Sept. 5, 2013) (same). At most, Defendants' motion raises issues of fact not appropriate for resolution at this stage of the proceedings.

On March 3, 2015, the City of Providence, R.I. (hereinafter, "Providence") filed a related action against Celgene, which has been transferred to your Honor. *See* 2:15-cv-01605-KSH-CLW, Dkt. 1. The parties have stipulated to consolidation of the cases, and Providence joins in this brief.

STATEMENT OF FACTS

A. Celgene's Abuse of the REMS Process Has Thwarted Competition, Undermining the Purpose of the Hatch-Waxman Act

Congress passed the Hatch-Waxman Act to "speed the introduction of low-cost generic drugs to market, thereby furthering drug competition." *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228 (2013) (internal citations and quotations omitted). The FTC states that generic drugs typically cost 20 to 70% less than their branded counterparts. *Generic Drugs and Low-Cost Prescriptions*, Federal Trade Commission, available at http://www.consumer.ftc.gov/articles/0063-generic-drugs-and-low-cost-prescriptions; *see also* Compl. ¶ 57.

To facilitate the entry of lower cost generics, the Hatch-Waxman Act established an Abbreviated New Drug Application ("ANDA") process for generic

drug approval. Compl. ¶ 25. The ANDA process allows a generic applicant to demonstrate bioequivalence to the branded drug, rather than replicate full clinical trials required for a New Drug Application ("NDA"). *Id.*; *see* 21 U.S.C. § 355(j); *see generally Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). To demonstrate bioequivalence, a generic manufacturer must obtain samples of the branded drug. Typically, a generic manufacturer obtains the necessary samples through normal distribution channels (*e.g.*, purchasing from a wholesaler). Compl. ¶¶ 5; 87. However, because Thalomid and Revlimid are subject to restricted distribution programs (referred to as "REMS" programs) due to their potentially dangerous side effects, generic manufacturers are required to obtain the necessary samples of the drugs directly from Celgene. Compl. ¶¶ 68-69.

As part of its anticompetitive scheme to prevent generic competition, Celgene has refused to provide the necessary samples to its would-be generic competitors, including Mylan Pharmaceuticals ("Mylan") between 2004 and the present, Lannett Company ("Lannett") in 2006, and Dr. Reddy's Laboratories ("Dr. Reddy's") in 2008 and 2009. Compl. ¶ 71. In direct contravention of the 2007 Food and Drug Administration Amendments Act (which forbids brand firms from abusing the REMS process to "block or delay" generic entry), Celgene has utilized the REMS program's distribution restrictions as a pretext for refusing to provide samples to generic competitors. Compl. ¶¶ 72-74; FDC Act § 505-1(f)(8).

Additionally, despite its stated concerns regarding the REMS programs, Celgene has provided Thalomid and Revlimid to research organizations that do not compete with it. Compl. ¶¶ 76-77. Moreover, these purported REMS concerns should have been alleviated by the FDA's letters to Celgene confirming that it may sell Thalomid and Revlimid to generic competitors for bioequivalence testing without violating REMS. Compl. ¶¶ 75, 89-93, 101-108, 120-121.

Celgene controls 100% of the markets for Thalomid and Revlimid, and is able to charge extraordinarily high monopoly prices (approximately $8,000 to $10,000 per month for Thalomid and $15,000 to $20,000 per month for Revlimid). Compl. ¶¶ 3, 67-69.

B. Celgene's Practice of Engaging in Sham Litigation against Generic Competitors Has Obstructed Generic Competition

The Hatch-Waxman Act also facilitates expeditious resolution of any patent-related disputes between branded and generic drug manufacturers. Compl. ¶¶ 30, 38-39; H.R. Rep. No. 857, 98th Cong., 2d Sess., Pt. 1, at 14-17 (1984) (House Report); *id.* Pt. 2, at 5-6. The ANDA must explain how the generic drug can be marketed without infringing certain of the branded manufacturer's patents listed in the Orange Book. *See* 21 U.S.C. § 355(j)(2)(A)(vii)-(viii). The generic manufacturer may file a "paragraph IV certification," stating that the patents asserted by the branded manufacturer are "invalid or will not be infringed by the manufacture, use, or sale of the [generic] drug." *Caraco Pharm. Labs*, 132 S. Ct. at

1677 (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)). The paragraph IV certification constitutes a statutory act of infringement that allows the branded manufacturer to sue for patent infringement. The suit will then be litigated, but in 73% of cases, the generic manufacturer prevails and is able to bring its drug to market. Compl. ¶ 41; FTC, Generic Drug Entry Prior to Patent Expiration 10, 19-20 (July 2002) (*Generic Drug Entry*) (finding that generic competitors prevailed over branded manufacturers with respect to 73% of the drug products that were the subject of a court decision on paragraph IV patent litigation initiated between 1992 and 2000), available at http://www.ftc.gov/os/2002/07/genericdrugsstudy.pdf.

In those rare circumstances where a competitor managed to obtain samples of Thalomid or Revlimid to perform bioequivalence testing, and then submitted an ANDA with a paragraph IV certification, Celgene has blocked the generics by filing sham lawsuits against them. Compl. ¶¶ 211-238. Celgene knew that the patents it sued Barr and Natco for allegedly infringing with their generic versions of Thalomid and Revlimid were invalid and/or unenforceable (in some instances because the patents were obtained by fraud). Compl. ¶¶ 213-224. Thus, Celgene brought these lawsuits for the sole purpose of delaying generic competition to Thalomid or Revlimid. Compl. ¶¶ 212, 223-224. After losing its motion to bifurcate discovery of Barr's antitrust counterclaims, Celgene settled on confidential terms with Barr, and Barr has not subsequently marketed generic

Thalomid. Compl. ¶¶ 216-19. Celgene's patent infringement lawsuit against Natco, which is still pending, has had the anticompetitive effect of keeping generic alternatives to Revlimid off the market. Compl. ¶¶ 212, 238. As a result of Celgene's anticompetitive conduct, the Class has been forced to pay supracompetitive prices for these life-saving drugs.

ARGUMENT

To defeat a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a complaint must allege "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "[S]tating ... a claim requires a complaint with enough factual matter (taken as true) to… raise a reasonable expectation that discovery will reveal evidence of the required element." *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 234 (3d. Cir. 2008).

Far from a "formulaic recitation of the elements of a cause of action" (Def. Mem. at 11), Plaintiff's 75-page complaint details years of Celgene's anticompetitive conduct and adequately alleges sufficient facts to survive a motion to dismiss. At the pleading stage, Plaintiff need not *prove* that Celgene's conduct violated the Sherman Act, or that Celgene's conduct caused Plaintiff antitrust injury; it need only make "some showing sufficient to justify moving the case beyond the pleadings to the next stage of litigation." *Phillips*, 515 F.3d at 234-35 (*Twombly* "does not impose a probability requirement at the pleading stage").

Furthermore, "it is inappropriate to apply *Twombly*'s plausibility standard with extra bite in antitrust and other complex cases." *W. Penn Allegheny Health Sys. Inc. v. UPMC*, 627 F.3d 85, 98 (3d Cir. 2010).

I. PLAINTIFF HAS SUFFICIENTLY PLEADED AN OVERALL ILLEGAL ANTICOMPETITIVE SCHEME TO THWART GENERIC COMPETITION

Plaintiff has alleged that Celgene engaged in a multi-faceted scheme to maintain its monopoly and unlawfully interfere with competitors' efforts to enter the market with generic versions of Thalomid or Revlimid, including: (1) using FDA protocols that were designed to ensure safe access to these potentially dangerous drugs as a pretext to delay and indefinitely postpone the availability of cost-saving generic alternatives to these drugs; (2) fraudulently obtaining patents on the procedures regarding safe use of Thalomid and Revlimid in order to block generic entrants from coming to market; and (3) engaging in sham litigation against any generic competitor that managed to obtain samples of Thalomid or Revlimid that are necessary to perform bioequivalence testing. Compl. ¶¶ 4, 70-72, 94, 97, 119, 136, 211-212, *inter alia*.

Third Circuit law clearly establishes that the proper inquiry in an antitrust case is whether the defendant's alleged actions "considered together" harmed competition. *See LePage's Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003); *W. Penn*, 627 F.3d at 108; *In re Neurontin Antitrust Lit.*, 2009 WL 2751029, at *15 ("Courts

have routinely upheld the validity of 'overall monopolization scheme' claims in the patent context, even in the absence of allegations that any one of the scheme's predicate actions was independently violative of antitrust laws."); *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006) (same). Plaintiff challenges Celgene's conduct as a whole, and even if one aspect of Celgene's conduct was lawful, it may nevertheless be challenged as a part of Celgene's overall anticompetitive scheme to achieve and maintain monopoly power in violation of Section 2. *See In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 359 (D.N.J. 2009) (Hochberg, J.) (citing *Am. Tobacco Co. v. United States*, 328 U.S. 781, 809 (1946)).

Three judges within the Third Circuit have recently denied motions to dismiss lawsuits alleging virtually identical facts. *See* Transcript, *Mylan Pharms., Inc. v. Celgene Corp.*, No. 14-cv-2094 (D. N.J. Dec. 22, 2014) (Salas, J.), annexed as Exhibit A to the Accompanying Declaration of Frank R. Schirripa ("Schirripa Decl."); Order and Transcript, *Actelion Pharms. Ltd. v. Apotex*, Inc., No. 12-cv-5743-NLH, Dkt. 90, 93 (D.N.J. Oct. 17 and 23, 2013), Schirripa Decl. Ex. B ("Actelion Tr."); Order, *Lannett Co. v. Celgene Corp.*, No. 08-3920, Dkt. 27 (E.D. Pa. May 31, 2010), Dkt. 42 (March 31, 2011), Schirripa Decl. Ex. C. Most recently, in *Mylan v. Celgene*, Judge Salas denied Celgene's Motion to Dismiss (finding that Mylan had pleaded that Celgene was "motivated by its goal to obtain

long-term anticompetitive gain"), and the Third Circuit rejected Celgene's petition for interlocutory appeal on the same alleged "refusal to deal." Schirripa Decl. Ex. A at 17:20-23; *see also* Schirripa Decl. Ex. D, Order denying Celgene's Petition for Leave to File Interlocutory Appeal, *Mylan Pharms., Inc. v. Celgene Corp.*, No. 15-8017 (3d Cir. Mar. 5, 2015). Likewise, Judge Savage denied Celgene's motion to dismiss generic competitor Lannett's complaint, which challenged Celgene's anticompetitive refusal to provide samples of Thalomid to Lannett. Order, ECF No. 42, 08-cv-3920 (E.D. Pa. Mar. 31, 2011), Schirripa Decl. Ex. C; Compl., ECF No. 1, 08-cv-3920, Schirripa Decl. Ex. E.

Similarly, in *Actelion*, Judge Hillman denied the defendant's Motion to Dismiss on similar "refusals to deal," holding "that the determination of whether plaintiff's refusal to deal here, sell samples, amounts to protected and lawful conduct should await full discovery, and I will allow the case to proceed that way." *See* Schirripa Decl. Ex. B, *Actelion* Tr., at 115:10-13.

II. PLAINTIFF HAS SUFFICIENTLY PLEADED THAT CELGENE'S ANTICOMPETITIVE CONDUCT PREVENTED COMPETITORS FROM BRINGING GENERIC THALOMID AND REVLIMID TO MARKET, CAUSING ANTITRUST INJURY TO PLAINTIFF

Plaintiff pleaded that Celgene's anticompetitive conduct has prevented generic alternatives to Thalomid and Revlimid from coming to market, thereby causing its injury in the form of higher monopoly prices for these drugs. *See* Compl.¶¶ 6, 297, 309. These well-pleaded allegations defeat Celgene's challenges

to Plaintiff's standing and antitrust injury. *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 535 (D.N.J. 2004) (to adequately plead antitrust injury, "[p]laintiffs are simply required to allege facts showing that they suffered the type of injury or harm the antitrust laws were intended to prevent, and that their injury flows from the Defendants' anti-competitive conduct"); *In re Niaspan Antitrust Litig.*, No. 13-MD-2460, 2014 WL 4403848, at *15 (E.D. Pa. Sept. 5, 2014) ("More is not required at the pleading stage, particularly given that antitrust injury involves complex questions of fact, ill-suited for resolution on a motion to dismiss.") (internal quotations and citations omitted).

Rather than counter Plaintiff's actual allegations of Celgene's anticompetitive scheme, Celgene has invented a hypothetical future scenario, which it incorrectly maintains defeats any claim of antitrust injury. Celgene boldly states that it will sue all hypothetical future generic competitors (no matter whether the generic actually infringes Celgene's patents), and asks this Court to make a clairvoyant ruling that it would win these hypothetical cases. Celgene thereby reasons that generic competition from any source is impossible.

Celgene's alternative set of facts is speculative, unproven, and contradicts the well-pleaded facts the Court must accept as true. *See, e.g.*, Compl., ¶ 85 ("But for Celgene's interference, a lower-priced competing thalidomide generic product would have been introduced years earlier."); Compl., ¶ 244 ("But for Celgene's

anticompetitive conduct, generic Thalomid would have been brought to market long before the class period alleged here, which begins in 2010. Multiple competitors (Mylan beginning in 2004, and both Lannett and Barr in or before 2006) attempted to obtain Thalomid for bioequivalence testing, but were thwarted by Celgene."); Compl., ¶ 250 ("As a result of Celgene's anticompetitive conduct, Plaintiff and class members still do not have access to generic versions of either Thalomid or Revlimid."). It is well settled that "[d]ismissal under Rule 12(b)(6) is not permitted simply because Defendants can come up with a different set of facts that support an alternative possible cause for Plaintiffs' injury that does not offend antitrust law." *In re Cardizem CD Antitrust Litigation,* 105 F. Supp. 2d 618, 648-49 (2000); *see also In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d at 535 (the Court must accept the facts alleged by the plaintiff as true, and draw all reasonable inferences in the light most favorable to the plaintiff).

Like Celgene here, the defendant in *Cardizem* argued that the court was required "to determine whether plaintiffs *could have* suffered the same injury from *other conduct* (under a hypothetical set of facts that contradict those alleged in Plaintiff's complaint) that does not violate the antitrust laws." *Id.* at 647-48 (emphasis in original). The court disagreed, finding that a "plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving

compensable injury under § 4 of the Clayton Act." *Id.* at 649 (citing *Zenith Radio Corp. v. Hazeltine Research*, 395 U.S. 100, 114 n. 9 (1969)).

At the motion to dismiss stage, Plaintiff is not required to "adduce proofs discrediting all possible intervening causes of the delayed launch of generic products." *In re Neurontin Antitrust Litig*., 2009 WL 2751029, at *12; *In re Lipitor Antitrust Litig.*, 2013 WL 4780496, at *24 (holding that the plaintiffs adequately alleged that their injuries flowed from the branded drug manufacturer's anticompetitive conduct, despite the manufacturer's arguments that independent causes (including its own additional patents) would have prevented generic manufacturers from coming to market). In denying defendants' Motion to Dismiss in *In re K-Dur Antitrust Litigation*, this Court stated:

> In sum, Defendants have attempted to argue that Plaintiffs must allege (or dispose of) all alternative theories of causation to survive a motion to dismiss. This is not true at the pleading stage. Plaintiffs are simply required to allege facts showing that they suffered the type of injury or harm the antitrust laws were intended to prevent, and that their injury flows from the Defendants' anticompetitive conduct.

338 F. Supp. 2d at 535.

Causation is a "factual issue" – especially "where Defendants contest the allegation that generic competition would have and could have entered the market sooner but for Defendants' conduct." *In re Lipitor Antitrust Litig.*, 2013 WL 4780496, at *24 (finding that questions of the ability of generic competitors to

design around the defendant drug manufacturer's patents and to prevail in any infringement litigation were factual issues not to be resolved on a motion to dismiss). For these reasons, "the existence of antitrust injury is not typically resolved through motions to dismiss." *In re Neurontin Antitrust Litig.*, 2009 WL 2751029, at *11 (quoting *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 417 (3d Cir. 1997)).

A. The Mere Existence of Celgene's "Broad Patent Portfolio" Cannot Defeat Plaintiff's Allegations of Anticompetitive Injury on a Motion to Dismiss

While Celgene may have a "legally protected right to *assert* nearly three dozen patents," (Def. Memo. at 8), Celgene's assertion that it would prevail in every hypothetical patent infringement case for every possible future generic version of Thalomid or Revlimid is unsupported, and insufficient to defeat Plaintiff's allegation that Celgene's anticompetitive conduct has prevented generic entry. In fact, Celgene has never prevailed in its patent infringement lawsuits against would-be generic competitors for Thalomid and Revlimid; it settled with Barr on confidential terms, and its litigation with Natco and Lannett is ongoing. Moreover, the fact that Lannett, Dr. Reddy's, Barr, Mylan and Natco have all expended resources attempting to enter the Thalomid and/or Revlimid markets indicates that at least five experienced generic drug manufacturers believe they

could bring a generic equivalent to market, despite Celgene's "broad patent portfolio." Celgene has given this Court no reason to disregard the facts as pleaded.

In fact, taking Celgene's argument to its logical conclusion demonstrates its fallacy. If the existence of patents made all generic entry impossible, then the entire paragraph IV certification process (in which manufacturers of generic drugs explain how the patents on a branded drug are "invalid, or will not be infringed" by the generic) would be rendered useless. *Cf. Caraco Pharm. Labs*, 132 S. Ct. at 1677 (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)); FTC, Generic Drug Entry Prior to Patent Expiration 10, 19-20 (July 2002) (finding that generic competitors prevailed over branded manufacturers for 73% of the drug products in paragraph IV patent litigation decisions for cases initiated between 1992 and 2000), available at http://www.ftc.gov/os/2002/07/genericdrugsstudy.pdf; *see also* Paul Panicke & LiLan Ren, *Who Wins Patent Infringement Cases?*, 34 AIPLA Q.J. 1, 5 (2006) (finding that accused infringers had a 75% success rate in Federal Circuit decisions between 2002 and 2004 with a final ruling on drug-patent claims).

Whether a manufacturer has or could have developed a generic version of Thalomid or Revlimid that does not infringe Celgene's existing patents but for Celgene's anticompetitive conduct, or whether Celgene's patents would be found valid and enforceable, are disputed factual issues for the fact finder. *In re Lipitor Antitrust Litig.*, 2013 WL 4780496, at *24 (noting that the ability of generic

competitors to design around a defendants' patents, to prevail in any infringement litigation, and to gain FDA approval for whatever product they sought to market are factual issues).

The mere possibility that Celgene may one day assert certain patent rights against a competitor is not sufficient to bar Plaintiff's claims of monopolization. *See In re Neurontin Antitrust Litig.*, 2009 WL 2751029, at *11. Indeed, Celgene's promise to sue any potential generic competitor irrespective of whether it actually infringes underscores Plaintiff's allegation that Celgene routinely engaged in sham litigation to thwart competition. Compl. ¶¶ 4, 195, 211-238.

In addition, there are a number of weaknesses in Celgene's argument that it could indisputably block generic entry for both Thalomid and Revlimid, as illustrated by the following examples:

- According to Celgene's Ex. 3, Patent No. '327 is expired (and thus no longer enforceable).
- According to Celgene's Ex. 30, Patent No. '283 is held by the National Children's Medical Center – not Celgene – and thus Celgene would not have standing to bring a patent infringement lawsuit against a generic manufacturer for that patent.
- Fifteen of the patents asserted by Celgene in its Motion to Dismiss are within the same two patent families as the five distribution method patents and the '886 patent ("the Six Patents") alleged to be invalid and unenforceable because they were obtained by fraud on the PTO. Where, as here, claims across a number of patents are not materially different, the invalidity of one such claim is dispositive as to all claims. *See generally SmartGene, Inc. v. Advanced Biological Labs., SA*, 852 F. Supp. 2d 42, 46, n. 1 (D.D.C. 2012) (invalidity of a single claim invalidated all patents

at issue in the litigation because "the differences between the various method and system claims within the patents-in-dispute are immaterial."); *see, e.g.*, patents '763 (limiting safe distribution method to male patients) and '188 (same safe distribution method but not limited to male patients).

- Recent Supreme Court precedent has cast serious doubt on whether these distribution methods are actually patentable. *See Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1294-95 (2012) (invalidating patents that involved "well-understood, routine, conventional activity previously engaged in by researchers in the field"); *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2358 (2014) (adding a computer to an otherwise unpatentable process does not "transform a patent-ineligible" concept into a "patent-eligible invention"). Similarly, the distribution method patents here at issue involve well understood, routine, conventional activity, such as counseling patients about the risks that Thalomid and Revlimid pose to a fetus, obtaining informed consent from patients before administering the drug and using a computer to register patients taking the drugs. Thus, Celgene's distribution method patents may present no barrier to entry.

- Of the patents that Celgene alleges would operate to block generic entry of Thalomid and Revlimid, approximately one third have never been raised by Celgene in the various patent litigation cited in its motion to dismiss.

- Celgene's "more than forty patents" double-counts those it claims apply to both drugs, and misleadingly implies that each patent applies to each of the two drugs.

The foregoing examples raise a number of questions about Celgene's version of the facts, which must be construed in a light most favorable to the *plaintiff* at the motion to dismiss stage. For these reasons, the parties must be permitted to proceed to discovery and allowed to develop evidence of antitrust injury and causation to be evaluated by the finder of fact.

Moreover, Celgene muddles its causation argument with a request that this Court take judicial notice that "Celgene has a relevant patent portfolio of more than forty patents covering Thalomid and Revlimid." Def. Mem. at 15. In a footnote in *Morris v. Wyeth, Inc.* (the only legal support that Celgene cites in support of its request), the court took judicial notice that the Orange Book "identifies drug products approved on the basis of safety and effectiveness by the [FDA]." Civ. Action No. 09-0854, 2012 WL 601455, at *5 n.4 (W.D. La. Feb. 23, 2012).

While the Court may take judicial notice of the purpose of the Orange Book, it would be "a plainly improper use of the doctrine" to use judicial notice as a vehicle to find that Celgene's patents will prevent any competitor from bringing any generic version of either Thalomid or Revlimid to market. *See, e.g.*, *In re Niaspan Antitrust Litig*., 2014 WL 4403848, *13 (refusing to take judicial notice at motion to dismiss stage of documents that had been submitted in patent lawsuit as evidence that competitor would not have prevailed in patent litigation).

B. The Noerr-Pennington Doctrine Does Not Defeat Plaintiff's Allegations of Antitrust Injury on a Motion to Dismiss

By arguing that *Noerr-Pennington* protects it from all liability, Celgene misconstrues the *Noerr-Pennington* doctrine and Plaintiff's allegations. The *Noerr-Pennington* doctrine is an affirmative defense a party may assert to protect its past conduct from actual allegations of antitrust liability. *In re Gabapentin Patent Litig*., 649 F. Supp. 2d at 361. Celgene argues that because it holds patents that it

"indisputably *may* assert to protect its presumptively valid intellectual property," *Noerr-Pennington* would protect that conduct and Celgene could never be liable. Def. Memo. at 15 (emphasis added). However, as noted above, Celgene has not sued to enforce many of these patents. Moreover, Plaintiff has not alleged that Celgene should be held liable under the antitrust laws for hypothetical patent infringement lawsuits. Rather, Plaintiff alleges that Celgene has engaged in an anticompetitive scheme to prevent generic entry, including blocking access to samples for bioequivalence testing, committing fraud on the PTO, and filing actual sham patent lawsuits and citizen petitions (an exception to *Noerr-Pennington*). Neither does Plaintiff allege that Celgene should be liable for *every* claim it has made in a patent infringement lawsuit against a generic competitor through an exception to *Noerr-Pennington*. Instead, Plaintiff alleges that competitors would have prevailed in bringing generic Thalomid and Revlimid to market, but for Celgene's other anticompetitive conduct. The mere *existence* of other patents does not give Celgene carte blanche to engage in illegal monopolization under *Noerr-Pennington*.

III. PLAINTIFF HAS SUFFICIENTLY ALLEGED THAT CELGENE'S REFUSAL TO GRANT COMPETITORS ACCESS TO SAMPLES WAS PART OF AN ANTICOMPETITIVE SCHEME

Celgene has refused to sell Thalomid and Revlimid samples to generic competitors despite FDA authorization to do so and offers by the generic

competitors to pay full retail price – while simultaneously providing these samples to non-competitors. Compl. ¶¶ 70-122. The sole reason for Celgene's refusal to provide samples is to keep generic competitors from introducing lower-priced bioequivalents of Thalomid and Revlimid. *See id.* These allegations are sufficient to state a claim against Celgene for an anticompetitive "refusal to deal." *See Safeway Inc. v. Abbott Labs.*, 761 F. Supp. 2d 874, 894-95 (N.D. Cal. 2011) (holding that defendant's refusal to provide its competitors with a drug on the same terms it provided the drug to its retail customers could constitute anticompetitive refusal to deal); *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 408 (2004) ("Under certain circumstances a refusal to cooperate with rivals can constitute anticompetitive conduct…"); *Steward Health Care Sys., LLC v. Blue Cross & Blue Shield*, C.A. No. 13-405 S, 2014 U.S. Dist. LEXIS 20304, at *20 (D.R.I. Feb. 19, 2014) ("Courts have previously found an unlawful refusal to deal where the defendant would agree only to unreasonable terms and conditions amounting to a practical refusal to deal.").

Plaintiff has sufficiently pleaded that, as in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, Celgene has no legitimate business justification that would excuse its refusal to sell samples to any of its competitors, particularly when it was simultaneously providing samples to other entities. It refused to sell despite FDA approval to do so and despite the competitors' agreement to indemnify

Celgene from any liability. 472 U.S. 585, 592 (1985) (considering whether legitimate business justification explained other anticompetitive conduct); Compl. ¶¶ 75, 105-07; Mylan Compl. ¶¶ 108-121, 151-56, Schirripa Decl. Ex. F;. Lannett and Mylan, like Plaintiff, have alleged that Celgene's proffered safety concerns are pretextual. Compl. ¶¶ 95, 112-112, Schirripa Decl. Ex. E (Lannett Complaint). These allegations "support[] an inference that [Celgene] was not motivated by efficiency concerns and that it was willing to sacrifice short-run benefits . . . in exchange for a perceived long-run impact on [generic competition]." *Aspen Skiing*, 472 U.S. at 610-11.

In an attempt to conjure a business justification for preventing generic entry, Celgene again asks the court to take "judicial notice" that it would be liable for problems with the generic drugs, citing cases on failure to warn. Defs.' Mem. at 36. But the burden is *always* on the branded manufacturer to ensure the warning labels for its products are adequate, and Hatch-Waxman requires AB-rated generics to have labels *identical to the brand label*. *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574-75 (2011) ("A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. . . . A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's.") (citations

omitted). In other words, generic entry cannot impact Celgene's exposure for failure to warn because any liability will be based upon Celgene's *own* labeling.

Moreover, Celgene misconstrues and misapplies Supreme Court precedent. First, contrary to Celgene's argument, *Trinko* did not render refusals to deal *per se* lawful. Rather, it expressly preserved this theory of antitrust liability. 540 U.S. at 408-09. *Accord Nobody in Particular Presents, Inc. v. Clear Channel Commc'ns, Inc.*, 311 F. Supp. 2d 1048, 1107-08 (D. Colo. 2004). Nor does *Trinko* require a prior course of dealing. *Helicopter Transp. Servs., Inc. v. Erickson Air-Crane, Inc.*, No. CV-06-3077, 2008 WL 151833, at *9 (D. Or. Jan. 14, 2008) ("The Supreme Court has never held that termination of a preexisting course of dealing is a necessary element of an antitrust claim."). Additionally, unlike in *Trinko*, where the defendant's conduct had already been punished (and corrected) under the Telecommunications Act of 1996, and thus there was less "likelihood of major antitrust harm," Celgene's conduct remains uncorrected. Specifically, Celgene is *abusing* the regulatory structure to create antitrust harm and "the FDA does not have the regulatory power to compel samples and … there is no other potential remedy to … anticompetitive conduct in that regulatory scheme." Schirripa Decl. Ex. B, *Actelion* Tr. at 115:14-116:2. Secondly, *Pacific Bell Telephone Co. v. Linkline Communications, Inc.*, is inapposite because the plaintiffs in that case did not challenge the defendants' "duty to deal" – they instead alleged that the

defendants were engaged in an anticompetitive "price squeeze." 555 U.S. 438, 442, 445-46 (2009).

As in *Actelion*, this court should deny Defendant's request "to rule now on the scant record… on the pleadings themselves that its refusal to sell samples to its generic competitors is not illegal and cannot, on the facts pled, constitute a violation of Section 2…." Schirripa Decl. Ex. B, Actelion Tr. at 115:4-8. Plaintiff's allegations "support[] an inference that [Celgene] was not motivated by efficiency concerns and that it was willing to sacrifice short-run benefits . . . in exchange for a perceived long-run impact on [generic competition]." *Aspen Skiing*, 472 U.S. at 610-11. The existence and extent of business justifications is a factual question that cannot be resolved at the motion to dismiss stage. *See Covad Commc'ns Co. v. Bell Atl. Corp.*, 398 F.3d 666, 676 (D.C. Cir. 2005) ("Bell Atlantic's second defense—that its refusal to deal was economically justified—depends upon a question of fact and therefore is not cognizable in support of a motion to dismiss."). Plaintiff should be permitted to take discovery to prove whether Celgene's alleged safety concerns are a pretextual justification to extract monopoly profits. Schirripa Decl. Ex. B, *Actelion* Tr. at 115:10-13; 116:19-25.

IV. CELGENE'S SHAM LITIGATION AND FRAUD ON THE PTO ARE NOT PROTECTED BY *NOERR-PENNINGTON*

Plaintiff has sufficiently alleged that 1) Celgene brought "sham" litigation and a "sham" citizen's petition and 2) Celgene's conduct with respect to the Six

Patents constituted fraud on the PTO. Thus, *Noerr-Pennington* does not immunize Celgene's conduct. However, even if Celgene's past litigation for patent infringement were immune under *Noerr-Pennington*, the litigation is still relevant to Celgene's overall anticompetitive scheme. *See In re Neurontin Antitrust Litig.*, 2009 WL 2751029, at *17 ("even if [defendant] prevails on its *Noerr-Pennington* immunity arguments, evidence of any immune, yet allegedly anticompetitive, conduct may still be relevant to an evaluation of [defendant's] anticompetitive scheme, if such conduct is causally linked to the scheme."); *see also Hynix Semiconductor, Inc. v. Rambus, Inc.*, 527 F. Supp. 2d 1084 (N.D. Cal. 2007) (finding that protected petitioning conduct may be considered by the court where it is causally connected to other anticompetitive activity).

Here, because Celgene's patent infringement litigation is causally connected to its overall anticompetitive scheme (first blocking competitors' access to its drug for bioequivalence testing, and then suing those same competitors when they managed to obtain the drug and file an ANDA), any otherwise *Noerr-Pennington*-protected patent litigation is relevant to Celgene's scheme. *See Hynix Semiconductor Inc.*, 527 F. Supp. 2d at 1098 (finding that because defendants' alleged conduct independently qualified as anticompetitive harm under section 2, current patent litigation is "causally connected" to that behavior and therefore properly included in "anticompetitive scheme" allegation).

A. Celgene's Sham Litigation and Sham Citizen Petition Are Not Entitled to *Noerr-Pennington* Immunity

Plaintiff has adequately alleged that Celgene's patent litigation and citizen petition were a "sham," and, thus, Celgene is not entitled to *Noerr-Pennington* immunity. *Noerr-Pennington* immunity is not absolute but is, instead, subject to an exception for activities that are a "mere sham to cover . . . an attempt to interfere directly with the business relationships of a competitor." *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 56 (1993) ("*PRE*"). A defendant's otherwise protected conduct is actionable where, first, it is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits," *In re Wellbutrin XL Antitrust Litig.*, No. CIV.A. 08-2431, 2012 WL 1657734, at *4-5 (E.D. Pa. May 11, 2012) (citing *PRE*, 508 U.S. at 60). Once a court determines that the defendant's conduct is "objectively baseless," it then considers whether "the baseless suit or petition conceals an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process – as opposed to the outcome of that process – as an anticompetitive weapon." *Id.* (citing *PRE*, 508 U.S. at 61).

Plaintiff alleges that Celgene knew when it filed patent infringement suits against generic competitors that its patents were invalid and unenforceable (the Six Patents having been obtained through fraud on the PTO). As a result, Celgene knew the lawsuits were unlikely to be successful, and thus were objectively

baseless. *See, e.g.*, Section IV.B, *infra*; Compl. ¶¶ 131-148 (prior art references rendered the Six Patents invalid); Compl. ¶¶ 212, 218, 236, 238 (Celgene knew its other patents were unenforceable as obvious); *Abbott Labs.*, 432 F. Supp. 2d at 428 ("the objective prong of the PRE test requires an inquiry into the reasonableness of the belief that the litigation will be successful on the merits"). Merely by filing these lawsuits, Celgene obtained an automatic 30-month stay on generic competition under the Hatch-Waxman Act. Compl. ¶¶ 34, 194, 215; 21 U.S.C. § 355(j)(5)(B)(iii). Plaintiff alleges that Celgene's "sole purpose" in bringing these cases was as an "anticompetitive weapon" – to "delay generic entry." Compl. ¶ 212.

Plaintiff's "sham" allegations are not limited to baseless patent infringement cases. Plaintiff also alleges that Celgene filed a sham citizen petition with the FDA in an attempt to slow approval of a generic Thalomid. *Id.* at ¶ 220. The petition lacked any reasonable regulatory, scientific, medical, or other reasonable basis, because the FDA lacked the statutory authority to withhold approval of generic Thalomid on the bases cited by Celgene, or to require the actions Celgene sought to impose. *Id.* ¶¶ 223-24; *In re Flonase Antitrust Litig.*, 884 F. Supp. 2d 184, 191 (E.D. Pa. 2012) (evaluating evidence of sham citizen petition under *Noerr-Pennington*). Thus, it was "filed for the sole purpose of preventing competition by

delaying and foreclosing the FDA approval of generic Thalomid capsule ANDAs." *Id.*

Plaintiff's allegations that Celgene's actions were objectively baseless and used as an "anticompetitive weapon," are sufficient to defeat a motion to dismiss. *See Hoffman–LaRoche, Inc. v. Genpharm, Inc.*, 50 F. Supp. 2d 367, 380 (D.N.J. 1999) (whether a reasonable litigant would have realistically expected success on the merits of a patent infringement suit is a question of fact that cannot be determined on a motion to dismiss); *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d at 363-64 (denying motion to dismiss because knowledge of actual non-infringement was a disputed factual issue that the court must submit to the jury).

Celgene's assertion that Plaintiff must plead "*Walker Process*" fraud in order to properly allege that Celgene engaged in sham litigation is without merit. Def. Memo. at 31. As the court in *Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.* made clear: "a sham litigation claim based on inequitable conduct is not an end-run around the requirements of *Walker Process;* it is, instead, a different claim, predicated on the objective and subjective reasonableness for bringing the lawsuit, rather than on the conduct before the Patent Office." 432 F. Supp. 2d at 427; *see also Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1072 (Fed. Cir. 1998) (for a sham litigation claim, "[i]n contrast with a *Walker Process* claim, a patentee's activities in procuring the patent are not necessarily at issue. It

is the bringing of the lawsuit that is subjectively and objectively baseless that must be proved."). Importantly, "[e]ither theory may be used to overcome *Noerr* immunity." *Abbott Labs.*, 432 F. Supp. 2d at 427.

B. Plaintiff Has Adequately Pleaded Fraud on the PTO

Although Plaintiff's claims sufficiently overcome *Noerr-Pennington* under the "sham" litigation exception, Plaintiff has also sufficiently pleaded a claim of fraud on the PTO. Allegations of fraud on the PTO should include: "(1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998).

Plaintiff's Complaint itemizes numerous prior art references that Celgene failed to disclose to the PTO when applying for the Six Patents. Compl. ¶ 131. In more than 15 pages of the Complaint, Plaintiff details both the content of each of the alleged undisclosed prior art references and how Celgene's Six Patents were preempted by that prior art. *Id.* at ¶¶ 131-148. Additionally, Plaintiff alleges that the applicants for the Six Patents, as well as "agents, their attorneys and/or others substantively involved in prosecution" withheld the prior art from the PTO with the intent to deceive the Patent Examiner. *Id.* at ¶ 190. Finally, the Complaint

alleges that those same parties knowingly and willfully misrepresented and omitted material information during pendency of the applications and, but for these misrepresentations and omissions, the Six Patents would not have issued. *Id*. at ¶ 191. These facts, considered together, are sufficient to state a claim for fraud on the PTO. *See LG Elecs., Inc. v. ASKO Appliances, Inc.*, No. CIV.A. 08-828 (JAP), 2010 WL 1377255, at *3 (D. Del. Mar. 29, 2010).

V. PLAINTIFF HAS ADEQUATELY PLEADED STATE LAW DAMAGE CLAIMS

A. End Payors Have Standing to Pursue Claims Under the Laws of the States Where They, Their Members and Other Class Members Purchased or Provided Reimbursement for the Drugs at Issue

1. Plaintiff has Article III Standing

Defendant concedes, at a minimum, that IUB has standing to bring claims under the laws of Connecticut, Massachusetts, and Nebraska. Def. Mem. at 20. (Under the same logic, Providence has standing under Rhode Island, Florida, Kansas, Massachusetts, New Jersey, North Carolina, and Pennsylvania law.)

Celgene argues that IUB does not have Article III standing to assert claims on behalf of absent class members in states where IUB does not reside or has not paid for the drugs. Def. Mem. at 20-21. Celgene improperly confuses "standing" with class certification issues. The issues of whether a plaintiff has Article III standing to sue under a particular state law for individual recovery, and the ability to assert a claim under Fed. R. Civ. P. 23 on behalf of unnamed residents of other

states, are separate and distinct. *Meyer v. CUNA Mut. Grp.*, No. Civ. A. 03-602, 2006 U.S. Dist. LEXIS 4478, at *37 (W.D. Pa. Jan. 25, 2006) ("While there is no additional standing requirement for plaintiff who seeks to represent a class, questions relating to Article III standing, however, frequently overlap and are sometimes confused with criteria required for class certification embodied in Fed. R. Civ. P. 23(a)") (citations omitted).

To demonstrate Article III standing, a plaintiff need only show that "he personally has suffered some actual or threatened injury as a result of the putatively illegal conduct of the defendant." *Gladstone, Realtors v. Vill. of Bellwood*, 441 U.S. 91, 99 (1979). Here, Plaintiff plainly has Article III standing to pursue its own individual claims, as well as claims on behalf of the class. The Complaint alleges that, as a result of Celgene's anticompetitive tactics, Plaintiff paid more than it otherwise would have. Compl. ¶ 6.

2. Plaintiff's Ability to Pursue Claims of Absent Class Members Is An Issue Reserved for Class Certification Under Rule 23

Plaintiff has not brought claims in its own name in other states; rather, it seeks to represent similarly situated persons in other states. This issue, improperly raised by Defendant on a motion to dismiss, must ultimately be addressed at class certification under Rule 23. *See Ramirez v. STI Prepaid LLC*, 644 F. Supp. 2d 496, 505 (D.N.J. 2009) (holding that named plaintiffs' individual standing to allege violations of laws in states other than those in which they purchased defendants'

product is immaterial because the issue is one of predominance); *In Re Hypodermic Prods. Antitrust Litig.*, No. 05 CV 1602 JLL/CCC, 2007 WL 1959225, at *15 (D.N.J. June 29, 2007) (declining to rule on antitrust standing issue prior to class certification); *see also Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 612 (1997) (following Third Circuit in declining to reach standing issues because they would not exist if class were not certified); *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 377 (S.D.N.Y. 2002) (holding that alleged problems surrounding personal standing will not arise unless class certification is granted); *Kuhl v. Guitar Ctr. Stores, Inc.*, No. 07-C-214, 2008 WL 656049, at *2-3 (N.D. Ill. Mar. 5, 2008) (issue of class standing is more appropriately addressed at time of class certification); *see also In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367, 404 (D. Mass. 2013) (named plaintiffs had standing because they allege that they paid supracompetitive prices in several states, and could represent class in other states because they had the same incentive to litigate those claims). This court should decline to follow the contrary cases cited by Celgene, suggesting that the adequacy of a class representative to bring claims on behalf of similarly situated persons in other states is a question of standing, and instead follow the many cases that reserve this question for class certification. For these reasons, and at this stage, Plaintiff should be permitted to proceed under each of the state laws asserted in the Complaint.

B. Defendant's Choice of Law Analysis is Premature and Incorrect

Celgene's attempt to impose a choice of law analysis is premature at this early stage of the litigation, and incorrect because Plaintiff has claims in those states where it suffered injury.

1. Defendant's Choice of Law Analysis is Premature

As demonstrated by the very cases Celgene cites, its attempt to carve up Plaintiff's claim using a choice of law analysis is premature on a motion to dismiss. *See In re K-Dur Antitrust Litig.*, MDL No. 1419, 2008 WL 2660783 (D.N.J. Mar. 19, 2008) (analyzing choice of law at summary judgment); *In re Rezulin Prods. Liab. Litig.*, 392 F. Supp. 2d 597 (S.D.N.Y. 2005) (same); *Am. Rockwool, Inc. v. Owens-Corning Fiberglas Corp.*, 640 F. Supp. 1411 (E.D.N.C. 1986) (same); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP*, No. 08-CV-0179, 2012 WL 4336218 (E.D.N.Y. Sept. 17, 2012) (same); *In re Ditropan XL Antitrust Litig.*, 529 F. Supp. 2d 1098 (N.D. Cal. 2007) (no choice of law analysis); *In re Lorazepam & Clorazepate Antitrust Litig.*, 295 F. Supp. 2d 30 (D.D.C. 2003) (same).

Courts have flatly refused to engage in a choice of law analysis prior to completion of class discovery where the class definition includes members who suffered harm in more states than those in which the named plaintiffs reside. *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d at 541 (unwilling to predict which state

law(s) would be applicable in event class is certified); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d at 404, n.61 (choice of law analysis would be premature before parties are able to engage in discovery); *In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 534 (E.D. Pa. 2010) (choice of law issues may be determined at or after class certification).

Defendant's choice of law analysis is too restrictive and improperly attempts to preclude IUB's claims under Massachusetts and Nebraska law, as well as those claims pleaded by Providence under the laws of Rhode Island, Florida, Kansas, New Jersey, North Carolina, and Pennsylvania. The fact that Plaintiff has not alleged any claims under Connecticut law is of no moment and does not change the significant interests each named state has in protecting its residents who purchased Thalomid or Revlimid.

2. Plaintiff Has Claims Under The Laws of Its Home State and The Laws of States Where It Reimbursed its Members

Even if this Court decides to entertain a choice of law analysis, Plaintiff's claims are governed by the laws of the location where they suffered injury – *i.e.*, the state where Plaintiff itself is located (the "home" state) and the states where it paid for, or provided reimbursement for, Thalomid or Revlimid (the "purchase" states). *See In re Ductile Iron Pipe Fittings (DIPF) Indirect Purchaser Antitrust Litig.*, No. 12-CV-169, 2013 WL 5503308, at *12 (D.N.J. Oct. 2, 2013) (finding that indirect purchaser plaintiffs had standing to proceed with claims under state

law where they purchased defendant's products); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 13-MD-2445, 2014 WL 6792663, at *23 (E.D. Pa. Dec. 3, 2014) (holding that end payors may assert claims under laws of both home states and states where members purchased Suboxone); *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 157 (E.D. Pa. 2009) (holding that "plaintiffs' claims have clear connection to the states where the plaintiffs themselves are located and the states where their members made purchases of Wellbutrin XL"); *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 263 F.R.D. 205 (E.D. Pa. 2009) (each state's strong interest in protecting its residents dictates that law of that state governs overcharge injury arising in that state). Celgene concedes that plaintiffs have standing to assert state law claims in the purchase states. *See In re Magnesium Oxide Antitrust Litig.*, No. CIV. 10-5943 DRD, 2011 WL 5008090, at *7 (D.N.J. Oct. 20, 2011) (noting that defendant conceded plaintiff had standing to assert state law claims in states where plaintiffs purchased defendant's products).

Here, each of the states where the overcharges were incurred (between IUB and Providence, this includes Massachusetts, Nebraska, Florida, Kansas, Massachusetts, New Jersey, North Carolina, Pennsylvania, and Rhode Island), has a significant interest in protecting its own residents. Compl. ¶ 12; Providence Compl. ¶¶ 14. This interest is crucial when engaging in a choice of law analysis.

Restatement (Second) of Conflict of Laws § 6(2)(c) (factors include "the relevant policies of other states and the relative interests of those states in the determination of the particular issue"). Celgene's reliance on Restatement (Second) of Conflict of Laws § 145, cmt. E, which discusses choice of law where the state in which the injury occurred has no interest in the matter, is misplaced. To hold that IUB may pursue claims only in its principal place of business would be improvident because it would risk jeopardizing the interests of other members of the putative class who purchased Revlimid and Thalomid in other states. *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d at 404.

Under established antitrust jurisprudence and the plain language of the state statutes themselves, at a minimum, Plaintiff properly states claims under the laws of the states where they purchased or reimbursed purchases of Thalomid and Revlimid. Compl. ¶ 12.

C. IUB's Individual Members Residing in Massachusetts Have Stated an Antitrust Claim Under Massachusetts Law

As discussed above, IUB has standing to pursue antitrust claims under the laws of Massachusetts and Nebraska (at a minimum) because that is where the overcharge for Thalomid and Revlimid was incurred by individual members of IUB. Defendant does not challenge Plaintiff's antitrust claims arising under Nebraska law. Compl. ¶¶ 289(n); 295(o); and 299(n).

IUB has sufficiently alleged a cause of action under Massachusetts consumer protection laws. The Massachusetts Supreme Court has ruled that indirect purchasers have standing to challenge anticompetitive conduct under its consumer protection act. *See Ciardi v. Hoffmann-La Roche, Ltd.*, 762 N.E.2d 303, 311-12 (Mass. 2002). Plaintiff has stated a claim under § 9 of Mass. Gen. L. Ch. 93A. IUB's members include individuals that reside in Massachusetts and made in-state purchases of Thalomid and Revlimid.

D. Plaintiff's State Law Claims Are Not Preempted by Federal Law

Plaintiff's state law claims that Celgene engaged in an overall anticompetitive scheme to prevent generic competition are not preempted by federal patent law. Unlike in the cases cited by Celgene, Plaintiff has *not* pleaded a separate *Walker Process* fraud claim. *See In re K-Dur Antitrust Litig.*, No. 01-1652, 2007 WL 5297755 at *23-25 (D.N.J. Mar. 1, 2007); *see also Daiichi Sankyo, Inc. v. Apotex, Inc*. No. 030937, 2009 WL 1437815 at *9 (D.N.J. May 19, 2009) (dismissing claims based on "nothing more than misconduct before the PTO"); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 544 (E.D.N.Y. 2005) (dismissing state antitrust claim that did "not allege any conduct other than conduct before the PTO"); *Semiconductor Energy Lab. v. Samsung Elecs. Co.*, 204 F.3d 1368 (Fed. Cir. 2000) (same); *In re Netflix Antitrust Litig.*, 506 F. Supp. 2d 308, 313 (N.D. Cal. 2007) (same). Rather, Plaintiff alleges *Walker*

Process fraud and "sham" litigation as one part of Celgene's overall scheme (which also involved refusals to provide samples, a sham citizen petition, etc.); courts regularly allow end payor claims of an overall competitive scheme, which include allegations of sham litigation on fraud on the USPTO, to go forward. *See, e.g.*, *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 737 F. Supp. 2d 380 (E.D. Pa. 2010) (allegations of monopolistic course of conduct, which included fraud on the USPTO, were sufficient for indirect purchasers to state monopolization claims under various state antitrust laws); *Abbott Labs. v. Teva Pharm.*, 432 F. Supp. 2d at 433 (permitting indirect purchaser's state law antitrust claims to go forward where allegations included fraud on the USPTO and sham litigation); *In re DDAVP Indirect Purchaser Antitrust Litig*. 903 F. Supp. 2d 198, 218 (S.D.N.Y. 2012) (same).

For example, in *DDAVP*, indirect purchaser plaintiffs pleaded not only fraud on the PTO, but also bad-faith enforcement of the patent: an invalid Orange Book listing, sham patent litigation, and a sham citizen petition. 903 F. Supp. 2d at 218. The court concluded that these claims were not preempted, noting that unfair competition claims involved different elements than claims of inequitable conduct before the PTO. The court reasoned that the alleged harm occurred not at the PTO, but "later in the marketplace, even though the conduct before the PTO might be used to prove it." *Id*. (internal citations omitted). Importantly, the *DDAVP* court

distinguished the facts of *K-Dur*, *Ciprofloxacin,* and *Daiichi* because of the absence of alleged conduct beyond fraud on the PTO. *Id.* at 217; 219.

Here, as in *DDAVP*, allowing Plaintiff's state law claims to proceed "would neither duplicate the wrongs addressed or the remedies available under the patent laws, nor impede or impair those laws" (*id*. at 219); rather, Plaintiff has alleged anticompetitive conduct that caused its injury in the marketplace, beyond what the patent laws protect. Thus, Plaintiff's state law claims are not preempted.

E. Plaintiff Has Sufficiently Stated A Claim For Unjust Enrichment Under the Laws of All States, the District of Columbia, and Territories in the United States Except Ohio and Indiana

Plaintiff has sufficiently pleaded a claim under generally applicable theories of unjust enrichment, which are "universally recognized causes of action that are materially the same throughout the United States." *Singer v. AT&T Corp.*, 185 F.R.D. 681, 692 (S.D. Fla. 1998); *see also In re Mercedes-Benz Tele Aid Litig.*, 257 F.R.D. 46, 58 (D.N.J. 2009). Specifically, Plaintiff has sufficiently pleaded that: Celgene received a benefit in the "nature of profits resulting from unlawful overcharges and monopoly profits" (Compl. ¶ 306); the financial benefits received by Celgene rightfully belong to the named Plaintiff and the Class (Compl. ¶ 310); and it would be inequitable to allow Celgene to retain its ill-gotten gains (Compl. ¶

311). Restatement of Restitution § 1 (1937); *see also In re K-Dur*, 338 F. Supp. 2d at 544; *In re Lorazepam*, 295 F. Supp. 2d at 50.

Although Celgene urges the Court to apply Connecticut law to *all* Class members' unjust enrichment claims, for the reasons discussed in Section V.B, *supra*, it is clear that at this early stage in the litigation, Defendant's choice of law analysis is premature and contrary to established precedent. *See also Hypodermic Prods.*, 2007 WL 1959225, at *16 (finding that it is premature at motion to dismiss stage to consider plaintiffs' claims of unjust enrichment on a state by state basis because the class has yet to be certified).

Even if these matters were not premature, Celgene's argument that Plaintiff's unjust enrichment claims are an "end-run" around statutory limitations against indirect purchasers (Def. Memo. at 27-28) has been expressly rejected by a number of courts. *See, e.g., King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 539-40 (E.D. Pa. 2010) (rejecting defendants' arguments that unjust enrichment claims by end payors constituted an impermissible "end run" around statutory limitations on antitrust claims.); *In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672, 679 (S.D. Fla. 2004) (unjust enrichment claims are viable regardless of applicable state antitrust laws); *In re Cardizem CD Antitrust Litig.*,105 F. Supp. 2d at 669-71. Defendant's reliance on *K-Dur* for a contrary proposition ignores the fact that, at the *motion to dismiss* stage, the court addressed

plaintiff's unjust enrichment claims under generally applicable theories of the law, not under each particular state statute. *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d at 544.

Finally, Celgene's argument regarding certification of a class on an unjust enrichment theory is similarly premature and contrary to well established authority. *See Neale v. Volvo Cars of N. Am. LLC*, No. 10-CV-04407 DMC JAD, 2011 WL 1362470, at *2 (D.N.J. Apr. 11, 2011) (denying as premature defendants' Motion to Dismiss where defendants argued that plaintiffs would not be able to satisfy requirements for class certification); *Mills v. Serv. First Credit Union*, No. 4:11-CV-686, 2011 WL 3236313, at *1 (M.D. Pa. July 28, 2011) (denying motion to dismiss in light of Third Circuit's emphasis on discovery as part of class certification process and paucity of precedent dismissing cases on class certification grounds based on face of complaint); *In re Terazosin Hydrochloride*, 220 F.R.D. at 698 (certifying class of indirect purchasers claiming unjust enrichment).

The cases relied upon by the Defendant for the contrary position are readily distinguishable from the current facts. For example, unlike in *Green v. Green Mountain Coffee Roasters, Inc.*, all class members paid higher prices for Thalomid or Revlimid as a result of Celgene's conduct. 279 F.R.D. 275, 285 (D.N.J. 2011) (only certain class members purchased defective coffee brewers). Similarly, the *In*

re Polyurethane Foam Antitrust Litigation involved individual factual determinations, which stemmed in part from the differences between various conspiring defendants. Here, where Celgene is the sole manufacturer, this is not an issue. 799 F. Supp. 2d 777, 786 (N.D. Ohio 2011).

Although Celgene will eventually have the opportunity to challenge Plaintiff's unjust enrichment claims under Rule 23, it must wait until a later stage of this case after the parties have had an opportunity to engage in discovery.

CONCLUSION

For the foregoing reasons, IUB respectfully submits that Celgene's Motion to Dismiss should be denied in its entirety.

Dated: March 17, 2015

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